

MEDICAL POLICY



SUBJECT: INTRAVASCULAR BRACHYTHERAPY	EFFECTIVE DATE: 09/16/99 REVISED DATE: 01/18/01, 01/17/02, 01/16/03, 02/19/04, 12/16/04, 10/20/05, 10/19/06, 10/18/07, 09/18/08, 08/20/09 ARCHIVED DATE: 07/15/10 EDITED DATE: 07/21/11, 07/19/12, 07/18/13, 07/17/14, 07/16/15, 07/21/16, 07/20/17, 07/19/18 PAGE: 1 OF: 8
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<ul style="list-style-type: none">• <i>If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.</i>• <i>If a commercial product (including an Essential Plan product) or a Medicaid product covers a specific service, medical policy criteria apply to the benefit.</i>• <i>If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.</i>	

POLICY STATEMENT:

Based upon our criteria and assessment of the peer-reviewed literature:

- I. Intravascular coronary brachytherapy with gamma or beta emitting radiation has been proven medically effective and therefore **medically appropriate** in the treatment of in-stent restenosis of a previously placed bare-metal stent in a native coronary artery.
- II. Intravascular coronary brachytherapy with gamma or beta emitting radiation has not been proven medically effective and therefore considered **investigational** in the treatment of in-stent restenosis of a drug eluting stent.
- III. Intravascular coronary brachytherapy with gamma radiation only has been proven medically effective and is therefore considered **medically appropriate** for treatment of in-stent restenosis of a non-native coronary artery (e.g., saphenous vein graft).
- IV. Intravascular coronary brachytherapy to reduce the risk of de novo restenosis in conjunction with PTA with or without stent placement is considered **investigational**.
- V. Intravascular brachytherapy of noncoronary arteries, including but not limited to the femoropopliteal system, has not been proven medically effective and is therefore considered **investigational**.

Refer to Corporate Medical Policy #11.01.03 regarding Experimental and Investigational Services.

POLICY GUIDELINES:

The Federal Employee Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.

DESCRIPTION:

Intravascular brachytherapy is a technique that utilizes ionizing radiation delivered via wires/catheters to treat hyperplastic growth within a vessel or stent. The aim of this treatment is to improve lumen patency and arterial blood flow and reduce the rate of restenosis, ultimately reducing the need for multiple percutaneous interventional procedures. Intravascular brachytherapy in conjunction with percutaneous transluminal angioplasty has been investigated primarily in the coronary arteries.

In the coronary arteries, two clinical applications of intravascular brachytherapy have been investigated:

- I. As a technique to reduce the risk of de novo restenosis after intracoronary stent placement (e.g., in-stent restenosis). The risk of restenosis in patients who undergo percutaneous transluminal coronary angioplasty (PTCA) for coronary artery disease is estimated at 30%–50%, based on angiographic studies. Placement of stents as an adjunct to PTCA is one strategy to reduce restenosis; it is estimated that approximately 75% of PTCAs performed in the United States include stent placement. However, even with stent placement, the restenosis rate (e.g., in-stent restenosis) is estimated at 20%. Intracoronary radiation has been investigated both as an alternative to stent placement to reduce

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the risk of restenosis and as a technique to reduce the risk of in-stent restenosis. This application of intracoronary brachytherapy is an off-label indication.

II. As a treatment of restenosis at the site of a prior intracoronary stent.

There is about a 20% risk of in-stent restenosis. Management of in-stent restenosis is frequently ineffective, with recurrence rates of 30% - 70%. Management has included PTCA alone, restenting, laser angioplasty, and rotational atherectomy. These therapies, however, are often ineffective, requiring medical management or surgical revascularization. Intracoronary brachytherapy is an alternative to these therapies for the management of in-stent restenosis. In-stent restenosis of a grafted vessel can also occur, as in the saphenous vein bypass graft. Blockage of this type of graft causes a 40 percent rate of graft failure at 10 years, leading to repeat PTCA/CABG surgeries and increased morbidity and mortality rates.

Intravascular brachytherapy has also been investigated as an adjunct to percutaneous transluminal angioplasty (PTA) of the central arterial and femoropopliteal systems, as a technique to reduce the risk of a de novo restenosis, either in native or grafted vessels, both with or without stent placement. There are several concerns regarding extrapolation of results of utilization of intravascular brachytherapy from the coronary system to other arterial systems. There is greater anatomic variability in systemic arteries than coronary arteries in factors such as length, diameter, thickness, curvature, and orientation. The larger size of non-coronary arteries will generally necessitate treatment with a high-energy gamma radiation source rather than the beta radiation, which is more commonly used for the coronary arteries. High-energy radiation sources cannot be administered in most catheterization labs or radiology suites, necessitating treatment in the radiation oncology department. This makes the logistics of treatment of the non-coronary arteries more complex compared to the coronary arteries. The use of adjunctive agents, such as stenting and antiplatelet drugs, while very common in the coronary arteries, is not as well established for systemic angioplasty. Stenting in non-coronary arterial systems has not been definitively shown to be superior to angioplasty alone, although many experts use it for certain types of lesions such as longer segments of the iliac artery or ostial lesions of the aortic branch vessels.

RATIONALE:

This policy regarding intravascular coronary radiation therapy is based on a 2000 BCBS Association TEC Assessment that offered the following observations and conclusions:

- I. There are four well-designed randomized clinical trials evaluating the effectiveness of brachytherapy for managing in-stent restenosis in native coronary vessels. The outcomes of these trials indicate that patients with in-stent restenosis treated with brachytherapy do better than patients treated with PTCA alone or with PTCA and stenting. Angiographic data at 6 to 9 months show significant reduction in the restenosis rate in brachytherapy patients. More importantly, patients receiving brachytherapy have statistically significant reduction in target lesion revascularization rates.
- II. There are no randomized controlled trials supporting the use of intracoronary brachytherapy for the prevention of restenosis.

The policy regarding intravascular femoropopliteal radiation therapy is based on a 2002 BCBS Association TEC Assessment that offered the following observations and conclusions:

- I. The scientific evidence consisted of two randomized trials comparing PTA plus brachytherapy with angioplasty alone. Both trials had limitations that precluded conclusions on whether brachytherapy is efficacious for the population under consideration. The Vienna-2 trial was unblinded and had no placebo control. It also enrolled heterogeneous subgroups of patients. The second trial was single blinded with a sham brachytherapy placebo control. However, this trial only reported on 22 patients and used an unusual outcome measure as primary outcome.
- II. The TEC Assessment concluded that the evidence was insufficient to permit scientific conclusions regarding brachytherapy as an adjunct to peripheral artery angioplasty.

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Treating restenosis of bare-metal stents in native coronary arteries:

With the evolving evidence of the success of drug-eluting stents, trials are comparing brachytherapy to drug-eluting stents to determine the appropriate role of brachytherapy in the treatment and prevention of restenosis. The use of intravascular brachytherapy has been decreasing with the increased use of drug-eluting stents, and its future role in the treatment of in-stent restenosis is uncertain.

Early studies comparing vascular brachytherapy versus drug eluting stents for the treatment of restenosis of bare metal stents in native coronary arteries lacked long term follow up. Three recent studies were identified that address this issue: 2 randomized controlled trials reporting 1-year (n=129) and 2-year (n=396) clinical outcomes and a retrospective cohort study with 3-year (n=360) outcomes. Most evidence of stent failure was symptom related in these studies as protocol angiography was limited to the initial 6-or 9-month follow-up. Park, et al. (2008) reported 1-year MACE (major adverse cardiovascular events) rates of 7.7 vs. 18.8% (p=0.07) in a study of 129 patients from Asia in the drug eluting stent (sirolimus) and vascular brachytherapy groups respectively. Ellis et al. (2008) reported 2-year target lesion revascularization rates of 10.1% and 21.6% (p=0.03, n=396) in the drug eluting stent (paclitaxel) and brachytherapy groups respectively. However, there were no significant differences between the 2 groups with regard to death, myocardial infarction, or target vessel thrombosis at 24 months. A 5-year follow-up for this study is planned. Lastly, 3-year MACE-free survival was 92.5% in the drug eluting stent (sirolimus) treated cohort and 82.4% (p=0.03) in the brachytherapy cohort in a retrospective registry review of 360 patients from Asia reported by Lee, et al. (2007). These medium-term results are important; however, more information is needed regarding the long-term safety and efficacy of drug eluting stents.

Treating restenosis in drug-eluting stents:

Two clinical case series reported on use of vascular brachytherapy to treat restenosis in a DES. The study by Torguson, et al. (n=61) compared outcomes with a prior consecutive series (n=50) treated with repeat DES. At 8 months after treatment, rates of target lesion and target vessel revascularization were similar in the two series, although the MACE rate was smaller in the vascular brachytherapy group than in the repeat DES group (9.8% versus 2.4%; p=0.044). The second case series (Price, et al) only included five patients, all with recurrent stenosis after sequential treatment with sirolimus- and paclitaxel-eluting stents. Further study is needed to determine if vascular brachytherapy is useful to treat restenosis in DES.

Preventing restenosis after primary PTCA with or without stent placement:

Five studies reported on use of vascular brachytherapy to prevent restenosis after primary percutaneous interventions, including three with long-term (3.8 to 5 years) follow-up (Gruberg, et al, Ferrero, et al. and Nikas, et al) and two with intermediate-term (9-16 months) follow-up. (Syeda, et al. and Geiger, et al.) The studies with long-term follow-up reported that early benefit from vascular brachytherapy was not sustained, because of delayed and progressive restenosis and thrombotic complications. In one of the studies (Nikas, et al.), the delayed restenosis and thrombosis occurred despite the use of combined antiplatelet therapy.

Based on assessment of peer-reviewed literature, there is insufficient evidence to permit scientific conclusions regarding the use of brachytherapy as an adjunct to non-coronary artery angioplasty. The scientific evidence consists of both randomized trials and case studies comparing PTA plus brachytherapy with angioplasty alone. Study limitations and findings preclude conclusions on whether brachytherapy is efficacious for the populations under consideration.

Treating or preventing restenosis after angioplasty in femoropopliteal arteries:

Two studies reported long-term follow-up after endovascular brachytherapy to prevent restenosis in femoropopliteal arteries treated with balloon angioplasty. (Wolfram, et al. and Diehm, et al) Both reported that brachytherapy delayed restenosis when measured after short-term follow-up, but these benefits were not sustained and the rates of restenosis were similar in treated and control groups with longer follow-up.

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The FDA has approved three brachytherapy delivery systems for in-stent restenosis: Cordis Checkmate System™ (iridium-192 seeds for gamma radiation), Novoste Beta-Cath System™ (strontium-90 for beta radiation), and the Galileo Intravascular Radiotherapy System™ (phosphorus-32 wire for beta radiation). These systems are intended for use in *intracoronary* brachytherapy only and all have similar labeling that limits the approved use of the devices to treatment of in-stent restenosis. No devices have been approved or recommended for approval for primary prevention of in-stent restenosis. There are currently no FDA-approved devices for brachytherapy of noncoronary arteries. As of May 2007, the CheckMate and Galileo systems and devices for intravascular brachytherapy are no longer available, having been discontinued by their respective manufacturers. The Beta-Cath system is now manufactured and distributed by Best Vascular Inc.

CODES: Number Description

Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.

CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.

Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

CPT:	36247	Selective catheter placement, arterial system; initial third order or more selective abdominal, pelvic, or lower extremity artery branch, within a vascular family
	36248	Selective catheter placement, arterial system; additional second order, third order and beyond, abdominal, pelvic, or lower extremity artery branch, within a vascular family (List in addition to code for initial second or third order vessel as appropriate)
	77770-77772	Remote afterloading high dose rate radionuclide interstitial or intracavity brachytherapy, includes basic dosimetry when performed (code range)
	92920-92921	Percutaneous transluminal coronary angioplasty (code range)
	92924-92925	Percutaneous transluminal coronary atherectomy, with coronary angioplasty (code range)
	92928-92929	Percutaneous transcatheter placement of intracoronary stent(s), with major coronary angioplasty when performed (code range)
	92933-92934	Percutaneous transluminal coronary atherectomy, with intracoronary stent, with coronary angioplasty when performed (code range)
	92937-92938	Percutaneous transluminal revascularization of or through coronary artery bypass graft (internal mammary, free arterial, venous), any combination of intracoronary stent, atherectomy and angioplasty, including distal protection when performed (code range)
	92941	Percutaneous transluminal revascularization of acute total/subtotal occlusion during acute myocardial infarction, coronary artery or coronary artery bypass graft, any combination of intracoronary stent, atherectomy and angioplasty, including aspiration thrombectomy when performed, single vessel
	92943-92944	Percutaneous transluminal revascularization of chronic total occlusion, coronary artery, coronary artery branch, or coronary artery bypass graft, any combination of intracoronary artery stent, atherectomy and angioplasty (code range)

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92974 Transcatheter placement of radiation delivery device for subsequent coronary intravascular brachytherapy (List separately in addition to code for primary procedure)

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HCPCS: C1719 Brachytherapy source, non stranded, non high dose rate iridium 192, per source
C2616 Brachytherapy source, non stranded, yttrium 90, per source
Q3001 Radioelements for brachytherapy, any type, each

ICD10: I20.0-I20.9 Angina pectoris (code range)
I24.0-I24.9 Acute ischemic heart disease (code range)
I25.10-I25.9 Chronic ischemic heart disease (code range)

Investigational codes:

I70.1 Atherosclerosis of renal artery
I70.2-I70.25 Atherosclerosis of native arteries of the extremities (code range)
I70.301-I70.799 Atherosclerosis bypass graft of the extremities (code range)
I73.9 Peripheral vascular disease, unspecified

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* key article

KEY WORDS:

Endovascular Radiation, Restenosis, Femoropopliteal system, Renal artery stenosis.

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently no National Coverage Determination (NCD) or Local Coverage Determination (LCD) for Brachytherapy.